Remarks

The Present Invention

The present invention is directed to a formulation comprising a lipid-regulating agent dissolved or dispersed in at least one oil and an emulsifier or emulsifier blend, the resulting mixture being capable of forming an emulsion upon dilution in an aqueous medium.

The Office Action

The Office Action made the following rejections: Claims 13-15 were rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter; Claims 13-15 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention; Claims 1, 7-9, 13-14 were rejected under 35 U.S.C. 102(b) as being anticipated by Krueger et al., (EP 0031603); and Claims 2-6, 10-12 and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Krueger et al., (EP 0031603) in view of Suzuki et al., (EP 0700678) and The Merck Index.

Discussion of 35 U.S.C. Sec. 101 and 112, Second Paragraph Rejections

Claims 13-15 have been cancelled. Accordingly, the rejections of these claims under 35 U.S.C. Sec. 101 and Sec. 112 second paragraph is moot.

Discussion of 35 U.S.C. Sec. 102(b) Rejection of Claims 1, 7-9 and 13-14 over Krueger et al.

Claims 1, 7-9, 13-14 were rejected under 35 U.S.C. 102(b) as being anticipated by Krueger et al., (EP 0031603). The Office Action stated that "Krueger et al., (EP 0031603) teaches an emulsion composition delivery system comprising a lipid regulating agent (p-hexadecylaminobenzoic acid sodium salt), sesame oil and an emulsifier, which is a sorbitan fatty

acid derivative, polysorbate 80, page 1, lines 17-22 and page 15, lines 25-34. Krueger et al., (EP 0031603) also teaches that the resulting suspension may be administered orally, page 15 lines 33-34." Krueger teaches a suspension or an emulsion of a drug and a surfactant. (Pg 4, lines 19-21). The claims, as presently amended, are directed to a solution of a fibrate in an oil and one or more emulsifiers. Neither fibrates, nor solutions, are disclosed in Krueger et al. Thus, the rejection of Claim 1 and 7-9, as presently amended, under 35 U.S.C. Sec. 102(b) as anticipated by Krueger et al. should be withdrawn.

Discussion of 35 U.S.C. Sec. 103(a) Rejection of Claims 2-6, 10-12 and 15 over Krueger et al. in view of Suzuki et al. and The Merck Index

Claims 2-6, 10-12 and 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Krueger et al., (EP 0031603) in view of Suzuki et al., (EP 0700678) and The Merck Index. The Office Action stated that "It would have been obvious for one of ordinary skill in the art at the time the invention was made to use any of the statins known to be antihyperlipidemic agent, e.g. simvastatin, pravastatin and atorvastatin (see The Merck Index, page 146) in the Krueger emulsion composition. It would have also been obvious to substitute any oil of vegetable origin for sesame oil in the emulsion composition of Krueger. Furthermore, it would have been obvious to employ a co-solvent in the oil-in-water emulsion composition of Krueger.

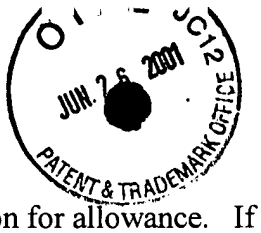
One of ordinary skill in the art would have been motivated to employ statins in the lipid regulating agent emulsion composition of Krueger because statins are known lipid-regulating agents, and are thus expected to be useful similar to as clofibrate, p-hexadecylaminobenzoic acid sodium salt, or other lipid-regulating agents in Krueger's composition. Similarly, one of ordinary skill in the art would have reasonably expected any pharmaceutically acceptable oil, including

soya bean oil, to be similarly useful in the oil-in-water emulsion composition of Krueger. See page 4, line 33-page 5 line 20 therein. Finally, the skilled artisan would have been motivated to use a co-solvent that does not effect the properties of the emulsion in order to improve the solubility as well as absorption of the lipid regulating agent in the host."

Suzuki et al. disclose a lipid emulsion composition comprising an oil component, an emulsifying agent containing yolk lecithin and/or soybean lecithin and water wherein the lipid emulsion contains citric acid or a pharmaceutically acceptable salt thereof and certain specified amino acids. The present invention does not require the use of citric acid or amino acids. → claim language is "comprising" it is OK Furthermore, Suzuki et al. does not teach solubilization of a lipid regulating agent as is claimed herein. Thus, there is no motivation to combine the teachings of Krueger et al and Suzuki et al. Furthermore, even if these references are properly combinable, they do not teach a fenofibrate composition in which fenofibrate is dissolved in oil with one or more emulsifiers as set forth in the claims. Withdrawal of the rejection of claims 3-6 and 10-12 under 35 U.S.C. Sec. 103(a) as unpatentable over Krueger et al. in view of Suzuki et al. and The Merck Index is respectfully requested.

Conclusion

The Applicants respectfully request favorable reconsideration and allowance of claims 1 and 3-12. It is urged that the subject application, as amended, is patentable over the references



and is in condition for allowance. If any fees are incurred as a result of the filing of this paper, authorization is given to charge Deposit Account Number 04-1644.

Respectfully submitted,

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CERTIFICATE OF EXPRESS MAILING

I hereby certify that the attached Amendment is being deposited with the United States Postal Service with sufficient postage as Express Mail No. EL746437763US in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on 6-26-01.

Carla Phillips

ersion with Markings to Show Changes

Claim 1 (once amended) A composition comprising a [lipid-regulating agent a] fibrate dissolved [or dispersed] in at least one oil with one or more emulsifiers, selected from the group consisting of [phospholipids,] polyoxyethylene sorbitan fatty acid derivatives, sorbitan fatty acid derivatives, [Polyoxyl-35-castor oil (Cremophor EL, available from BASF),] polyoxyl-35-castor oil, castor oil ethoxylates, [or] hydrogenated castor oil ethoxylates, polyglycerol esters of fatty acids, fatty acid ethoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropylene co-polymers, [and] polyoxyethylene-polyoxypropylene block co-polymers, [and TPGS (]d-alpha tocopheryl polyethylene glycol 1000 succinate[)] and combinations thereof wherein the resulting mixture [is capable of forming] forms an emulsion upon dilution with an aqueous phase.